August 2, 2002

Mr. Ronald A. Milner, Chief Operating Officer
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION'S OBSERVATION AUDIT REPORT NO. OAR-02-08, "OBSERVATION AUDIT OF THE BECHTEL SAIC COMPANY, LLC, AUDIT NO. BSC-02-028 OF THE GENERAL ELECTRIC GLOBAL RESEARCH AND DEVELOPMENT CENTER"

Dear Mr. Milner:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report No. OAR-02-08. It is on the U.S. Department of Energy's (DOE's), Office of Civilian Radioactive Waste Management (OCRWM), Management and Operating Contractor, Bechtel SAIC Company, LLC (BSC), Quality Assurance (QA) supplier audit of the General Electric Global Research and Development Center (GE Research), Schenectady, New York. This audit was conducted on June 25–26, 2002.

The purpose of this audit was to evaluate the effectiveness of the GE Research QA Program implementation, as delineated in the BSC procurement documents and technical services statement of work.

The scope of the audit included evaluating the implementation of the GE Research QA Program, associated QA Administrative Procedures, and technical test instructions, as applied to the stress-corrosion-crack growth rate and associated studies.

The NRC observers (observers) determined that the BSC audit was effective in identifying potential deficiencies and recommending improvements for the reviewed GE Research activities. During the conduct of the audit, both the BSC audit team (audit team) and the observers reviewed applicable documents, procedures, and activities within the audit's scope.

The audit team identified two potential quality observations in the areas of: (1) procurement, and (2) measuring and test equipment controls. The observers noted that the BSC audit was well-planned, thorough, and adequately evaluated the GE Research QA activities.

The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit meeting. The staff will continue to interface with OCRWM and follow the progress GE Research is making to address the issues identified during this audit.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Ted Carter of my staff at 301-415-6684.

Sincerely,
/RA/

Janet Schlueter, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: "NRC Observation Audit Report No. OAR–02–08,
'Observation Audit of the Bechtel SAIC Company,
LLC Audit No. BSC–SA–02–028 of General Electric
Global Research and Development Center' "

cc: See attached list

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OBSERVATION AUDIT REPORT NO. OAR–02–08,

"OBSERVATION AUDIT OF THE

BECHTEL SAIC COMPANY, LLC,

AUDIT NO. BSC–SA–02–028 OF THE GENERAL ELECTRIC

GLOBAL RESEARCH AND DEVELOPMENT CENTER"

/RA 08/01/02
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Reviewed and Approved by:

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Enclosure

1.0 INTRODUCTION

1.1 General Electric Global Research and Development Center Background

The current "Technical Services Statement of Work for GE Global Research and Development Center," Revision 02, January 23, 2001, describes experiments to measure stress-corrosion-crack initiation and growth rates under conditions that are both relevant and most likely to induce stress-corrosion cracking and to characterize the passive film characteristics and stability of Alloy 22 and titanium grade 7 materials. Three quality affecting tasks are involved: (1) Crack-Growth-Rate Studies, (2) Stress-Corrosion-Crack-Lifing Studies, and (3) Passive Film Characteristics and Long-Term Stability studies.

1.2 Audit Performance

Staff from the U.S. Nuclear Regulatory Commission (NRC), Division of Waste Management, and the Center for Nuclear Waste Regulatory Analyses (CNWRA) observed the Bechtel SAIC, LLC (BSC) audit of the implementation of the General Electric Global Research (GE Research) Quality Assurance (QA) Program, Corrosion Program Revision 1.1, dated December 20, 1996, as applicable to the testing activities being conducted. The audit was conducted on June 25–26, 2002, at the GE Research Laboratories, Schenectady, New York.

The purpose of this audit was to measure the effectiveness of the GE Research QA Program implementation as delineated in the BSC procurement documents and the technical services statement of work. The scope of the audit included evaluating the implementation of the GE Research QA Program and associated QA Administrative Procedures (QAAPs) and technical test instructions.

The NRC observers' (hereafter observers') objective was to assess whether the BSC QA, Product Quality Engineering/Supplier Audits and Evaluation Section, audit team (hereafter audit team) and GE were properly implementing the QA requirements contained under "Quality Assurance Criteria" in Part 63 of Title 10 of the U.S. Code of Federal Regulations (10 CFR Part 63) and to gain a better understanding of the corrosion-testing activities GE Research was conducting.

This report presents the observers' determination of the effectiveness of the BSC audit and whether GE Research implemented adequate controls in the audited areas.

2.0 MANAGEMENT SUMMARY

Within the areas evaluated, the audit team identified two potential quality observations. These discrepancies could be easily corrected and did not appear to impact the quality and technical adequacy of the GE Research products being supplied to BSC. The two potential quality observations identified were in the areas of: (1) procurement controls; and (2) control of measuring and test equipment. The staff believes that this BSC audit was well-planned, conducted in a professional and thorough manner, and adequately evaluated the GE Research QA activities.

The observers determined that BSC Audit No. BSC–SA–02–028 was effectively executed. The audit team members were independent of the activities they audited and were knowledgeable regarding the QA and technical disciplines within the scope of the audit. The observer team lead had previously reviewed the audit team members' qualifications and had found them acceptable.

3.0 AUDIT PARTICIPANTS

3.1 Observers

Thomas C. Trbovich—Team Leader, CNWRA
Tamara E. Bloomer—Technical Specialist, NRC

3.2 Audit Team

Daniel A. Klimas—Audit Team Leader, BSC QA
Robert D. Habbe—Auditor, BSC QA
Frank M.G. Wong—Technical Specialist, Management and Technical Services

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The BSC QA Audit of GE Research was conducted in accordance with the Office of Civilian Radioactive Waste Management Administrative Procedure (AP) AP–18.2Q, "Supplier Surveys/Audits," and any identified conditions adverse to quality were reported in accordance with AP–16.1Q, "Management of Conditions Adverse to Quality." The NRC staff's observation of this audit was based on NRC Manual Chapter 2110, "Conduct of Observation Audits," dated July 12, 2000.

4.1 Audit Scope

The scope of the audit was to evaluate the effectiveness of the GE Research QA Program, Corrosion Program Revision 1.1, dated December 20, 1996, that was developed to meet the requirements of the QA Program identified in the original procurement and the current Technical Statement of Work, Revision 2, dated January 23, 2001, and referenced in the BSC purchase order.

4.2 Audit Conduct and Timing

The audit was performed effectively and the audit team demonstrated a sound knowledge of the applicable GE Research programs and procedures. The audit checklist was developed using the GE Research QA Program and QAAP. Audit team members conducted thorough interviews; they challenged responses when appropriate; and they effectively employed their detailed checklists. The observers concluded that the timing of the audit was appropriate for the auditors to evaluate ongoing GE Research corrosion-crack-growth study activities. The audit team was able to observe the 150 stress-corrosion-cracking samples outside the autoclave system. In addition, the crack-growth-rate studies were completed on one set of

specimens and the second set was observed during testing. The audit team and the observers caucused at the end of each day. Audit team and GE Research management meetings were held as necessary, to discuss the current audit status and preliminary audit findings. The observers attended these meetings.

4.3 Audit Team Qualification and Independence

The audit team's qualifications, based on previous reviews, conformed to the requirements of the U.S. Department of Energy (DOE) Procedure (QAP)–18.1 "Auditor Qualification." The observers concluded that the audit team members had the necessary expertise to perform the audit and were qualified to audit the GE Research activities. The observers also concluded that the audit team members had sufficient authority and organizational freedom to make the audit process meaningful and effective.

4.4 Examination of the QA Elements

4.4.1 QA Program, Procedures, and Training—(QAAP 2-1, "Indoctrination and Training"; QAAP 2-2, "Personnel Qualifications")

The audit team reviewed the GE Research corrosion project organizational structure and determined that it provided adequate organizational freedom for the QA Project Officer to perform his independent functions. The audit team determined that adequate policies, procedures, and instructions were available and properly controlled for performing quality-related activities on the corrosion-crack-growth studies. The audit team provided several recommendations on various procedures to eliminate excessive details that were not necessary to satisfy the quality requirements specified in the BSC Technical Services Statement of Work.

Also, the audit team reviewed several indoctrination, training, and qualification records for various GE Research personnel involved with the crack-growth studies and found them acceptable. A recommendation was made to revise the procedure to make more use of the GE Corporate personnel forms, rather than generating a specific project form and attaching the GE Corporate form to it.

The observers agreed with the audit team's findings in this area.

4.4.2 Procurement Document Control—(QAAP 4-1)

The audit team reviewed several purchase orders for calibration services. The QAAP contains a listing of nine items that…"shall be included in the procurement documents as a minimum." It was determined that several of the procurement documents did not contain all of the nine items. It was also determined that a few of the nine items, such as the requirements in 10 CFR Part 50, Appendix B, and 10 CFR Part 21, were beyond the requirements necessary to meet the BSC Quality program. A potential Quality Observation was initiated to describe the deficiency.

The observers agreed with the audit team's findings in this area.

4.4.3 Control of Measuring and Test Equipment—(QAAP 12-1, "Calibration")

Calibration stickers on thermocouples in the Passive Film Characteristics and Long-Term Stability laboratories were labeled inconsistently with the equipment list and calibration log. Similarly, inconsistencies in the calibration schedule for one of the Instron machines were identified. The audit team brought these to the attention of the GE Research staff, which corrected them. A potential Quality Observation was initiated on the discrepancy. In addition, the master equipment list initially given to the observers was not up-to-date. The audit team brought this to the attention of the GE Research staff and the correct equipment list was located in the procedure book.

The observers agreed with the audit team findings in this area.

4.4.4 Scientific Investigation—(QAAP 11-1, "Test Control")

BSC does not require GE Research, in the purchase order/statement of work, to keep scientific notebooks to the level dictated in the QA and Requirements Description, Revision 11, Section III.2.2. However, the Technical Services Statement of Work for GE Research states that scientific investigation activities shall be documented in scientific notebooks that provide a description of both the planned work and the work actually performed, as well as the results. Two of the three notebooks the audit team reviewed had appropriate detail and were traceable. The third scientific notebook was problematic in that additional information had to be reviewed from other sources to get the complete information and make the notebook traceable. A recommendation was made by the audit team that GE Research should consider using a separate notebook for each of the different tests so the test could be easily understood, easily retraced, and the test easily repeated without recourse to the original investigator.

The observers agreed with the audit team findings in this area.

5.0 NRC STAFF FINDINGS

The observers determined that Audit No. BSC–SA–02–028 was effective in determining the level of compliance of the GE Research activities associated with the corrosion-crack-growth testing. The observers agreed with the audit team's conclusion that the purchase order, statement of work, and the GE quality program had been satisfactorily implemented, except for the identified potential observations.

The observers recommended that BSC should require GE Research to bring the scientific notebooks up to the standards set in the QA and Requirements Description. This was suggested because some of the results GE reported will be used as direct input into DOE's total system performance assessment code.

5.1 NRC Audit Exit Summary

During the audit exit meeting, the observers expressed appreciation for the excellent cooperation and responsiveness they received during their observation activities. In addition, the observers stated that they agreed with the audit team's findings and recommendations, as

presented at the audit exit meeting. Also, during the audit exit, the observers stated that they will continue to interface with DOE and BSC to follow the progress that GE Research is making to address the issues identified during this audit.

5.2 NRC Audit Observer Inquiries

There were no audit observer inquiries initiated as a result of Audit BSC–02–028. However, the open audit inquiry, LLNL–ARC–02–07, was discussed with the Bechtel/SAIC Procurement Quality Representative in order to explain the background and circumstances regarding the lack of documentation for receipt inspection performance. A response package has been prepared for management review.

The Audit Observer Inquiry, LLNL–ARC–02–7 remains open pending response.